Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2008889	05/09/2023
Name of Provider or Supplier	**Street Address, City, State**	
Arkansas Dermatology	1708 North Buerkle Rd, Stuttgart, AR	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Through review of the CMS 209 form, personnel records, and interview conducted on 5/9/2023 it was determined that the competency of the testing personnel was not assessed by the laboratory director on an annual basis. Findings follow: A) Review of personnel files for two of five testing personnel revealed that the annual evaluation of the competency of the testing personnel (number six on the CMS 209 form) was documented only once dated January 4, 2021, testing personnel (number seven the CMS 209 form) was documented only once dated March 9, 2021, and no other documentation of testing personnel competency was presented. B) Upon request, the laboratory was unable to provide other competency evaluations of the testing personnel (number six and seven on the CMS 209 form) after the evaluation identified above. C) In an interview on 5/9/2023 at 11:15 a.m. the testing personnel (number five on the CMS 209 form) said that no other competency evaluations were present and available.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity.

	(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Through observations made during a tour of the laboratory, review of manufacturer's instruction manual, review of the laboratory's temperature and humidity records and interviews with staff, it was determined the laboratory temperature and humidity was not monitored with the manufacturer's requirement for operating temperature and humidity for the laboratory's Avantik QS11 Cryostat. Survey findings include: A) During a tour of the laboratory on 5/9/2023 at 11:13 a.m., two Avantik QS11 Cryostat instruments were in an adjacent room next to the main laboratory with a closable door. B) Review of the manufacturer's instruction manual for the Avantik QS11 Cryostat revealed operating conditions: +5C up to +35C (at a max. rel. humidity of 60%). C) Review of the laboratory's room temperature and humidity log for Cryostat room for 2022 revealed days recorded of laboratory operation were forty-four. Temperature and humidity recorded in the Cryostat room zero out of forty-four. D) Review of the laboratory's room temperature and humidity log for Cryostat room for 2023 revealed days recorded of laboratory operation were nineteen. Temperature and humidity recorded in the Cryostat room zero out of nineteen. E) In an interview on 5/9 /23 at 11:13 a.m. the laboratory staff member (# 5 on the CMS 209 form) confirmed that the temperature and humidity requirement for Avantik QS11 Cryostat was not recorded.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Through a review of the CMS-209 form presented at the time of the survey, a review of personnel records for eight personnel listed on the form CMS-209, and through interviews with laboratory staff, it was determined five of eight testing personnel failed to have written authorization to perform testing without direct supervision. Survey findings include: A. Through a review of the CMS- 209 form, it was determined laboratory personnel # 4, # 5, # 6, # 7, and # 8, were designated as testing personnel. B. A review of personnel records for eight personnel listed on the form CMS-209 revealed that five of eight failed to have written authorization to perform testing without direct supervision. Laboratory personnel # 4, # 5, # 6, # 7, and # 8, did not have a written authorization to perform testing without direct supervision. C. In an interview at 11:13 a.m. on 5/9/2023, laboratory personnel # 5 (listed on the form CMS-209) confirmed that the laboratory did not have documented authorization for testing for employees performing testing.